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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,526	04/30/2001	Gary Maurice Dull	627-325IP	2781

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EXAMINER
BALASUBRAMANIAN, VENKATARAMAN

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 07/02/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/845,526	DULL ET AL.	
	Examiner	Art Unit	
	Venkataraman Balasubramanian	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,22-41,48-66 and 73-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *51-66 and 73-75* is/are allowed.

6)☒ Claim(s) *1,4-8,16,25,28-33 and 41* is/are rejected.

7)☒ Claim(s) *2,3,22-24,34-40 and 48-50* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicants' response, which included amendment to claims 1, 16, 25, 41, 51, and 61, filed on 4/14/2003, is made of record.

Claims 1-16, 22-41,48-66, and 73-75 are pending.

In view of applicants' response, particularly amendment to claims 1, 16, 41, 51,66, all 112 second paragraph rejection made in the previous office action have been obviated. Furthermore, in view of applicants' amendment to method of use claims 51, 66, to limit to specific diseases for which support is available in prior art, 112 first paragraph rejection made in the previous office action has been obviated. However, applicants should note that the traversal is not persuasive as it relies on WIPO document for support. 112 first paragraph issues are not strongly implemented in WIPO document and often they are published as is. Hence applicant argument that there is enablement in WIPO is not proper. However, for the diseases recited there are several prior art available and hence the rejection is deemed as obviated.

As for 103 rejection over Vernier et al., applicants should note that the restriction on the core has no bearing on the position of side chain attachment and that the traversal is based on misconception. However, one trained in the art has to make more than one variation in the compounds enabled by Vernier to arrive at the instant compounds, hence such positional variations are not deemed as obvious. Hence 103 rejection over Vernier et al. is deemed as obviated.

However, the following new rejection applies.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4-8, 16, 25, 28-33 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitmore et al. 5,731,323.

Determining the scope and contents of the prior art:

Whitmore et al. teaches several quinuclidine compounds, which generically include compounds, embraced in the instant claims for the use as Squalene synthase inhibitors for treating hyperchlosterolemia and atherosclerosis. See formula I on column 1-2 and 21 and note the definition of Ar, X, R_1 and R_2 , which generically include compounds claimed in the instant claims. Note when instant m plus n is zero, the compounds taught by Whitmore et al., is also claimed in the instant claims. See entire document for details. Examples 1-7 for compounds made shown on column 16-18.

Ascertaining the differences between the prior art and the claims at issue:

Instant claims require beside ethynyl compounds vinyl compounds with various substituents on the pyridine ring as well as quinuclidine ring.

Resolving the level of ordinary skill in the pertinent art:

However Whitmore et al. teaches the equivalency of exemplified pyridinyl-ethynyl quinuclidine compounds with those claimed for various X as seen in the definition of variable X for compound of formula I. See column 1 -2, formula I, especially the definitions of X, Ar, R^1, and R_2.

Considering objective evidence present in the application indicating obviousness or nonobviousness:

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make quinuclidine compounds variously substituted in Ar ring and with various X groups as permitted by the reference and expect resulting

compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

Allowable Subject Matter

Claims 2-3, 22-24, 34-40, and 48-50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 51-66 and 73-75 are allowed. Said claims would be allowed since specific species or composition or method of use embraced in these claims are not taught or suggested by the art of record or from a search in the relevant art area.

Information Disclosure Statement

References cited in the Supplemental Information Disclosure Statement (paper #7) are considered except for the International Search Report, which is not a publication per se and thus not properly cited as such in the Information Disclosure Statement. See MPEP 2205.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 6/13/2003 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

VB
V. Balasubramanian

6/28/2003

Mukund J. Shah
MUKUND J. SHAH
SUPERVISORY PATENT EXAMINER
GROUP 1200